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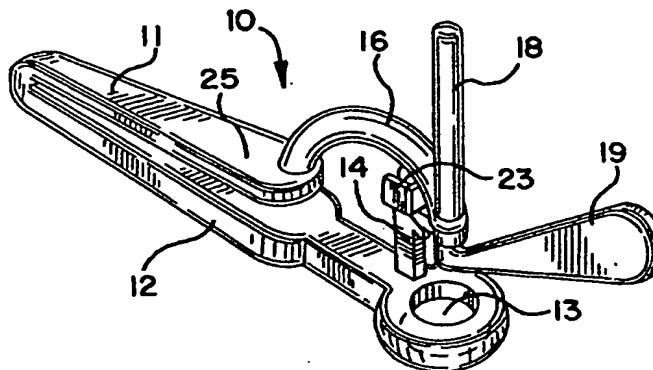
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(21) International Application Number: PCT/US93/12098 (22) International Filing Date: 13 December 1993 (13.12.93) (71) Applicant: DAVIS MANUFACTURING SYSTEMS, INC. [US/US]; 303 Delles Road, Wheaton, IL 60187 (US). (72) Inventor: DAVIS, D. J., Jr. ; 1351 Portsmouth, Carol Stream, IL 60188 (US). (74) Agents: SHEKLETON, Gerald, T. et al. ; Welsh & Katz, Ltd., Suite 1625, 135 South LaSalle Street, Chicago, IL 60603 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: **BLOOD LANCING DEVICE**

(57) Abstract

This invention is a device for lancing fingers and related body portions for purposes of drawing blood comprising opposing arms (11) (12) integrally joined at an acute angle. A lancing blade at one end is poised for travel through an aperture (13) in the opposing arm (12), and separated until use by mating stop members (30, 31). Pressure on the upper arm causes the stop members to slide past one another and the blade snaps through the aperture to lance the finger, whereupon it immediately retracts to an unexposed position.



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BLOOD LANCING DEVICE

Background of the Invention

This invention relates to a surgical lancet for drawing blood for collection and analysis. More particularly, this invention relates to a disposable one-use lancet for the drawing of blood.

In certain blood collection procedures, only a small amount of blood is necessary, which small amount may be procured through a lancing technique with a simple pin-like lance mounted in a plastic handle and used with a stabbing motion. However, the use of this pin-like device requires a certain amount of skill to aim and stab to the required depth. Too shallow of a stab will result in insufficient blood, while too deep of a stab may cause excessive pain. In addition, the lancing device should be sterile and easy to use. Thus, a single use, disposable lancing device holds attraction as it would avoid the risk of cross-contamination and the possible spread of infectious disease from this source.

Accordingly, it is an object of the subject invention to provide an improved lancing device for lancing a finger or other skin area of the patient for the purpose of obtaining a blood sample.

Another object of the subject invention is to provide a lancing device at a low cost to make single use and disposability possible.

1 Another object of the subject invention is a
2 blood lancing device which operates with a positive action
3 lancing movement.

4 The above objects are accomplished with the
5 device of the subject invention which comprises essentially
6 a V-shaped spring member having a coaxing pair of arms.
7 A lancing blade is carried in a transverse position on an
8 upper arm and positioned for reciprocal movement through
9 and away from an opening in the opposing arm. In use, the
10 opening is positioned over a position of the finger and the
11 lancing blade used to draw blood as will be described. A
12 cocking device located about the opening interacts with and
13 limits movement of the lancing blade by means of a catch
14 member both before and after use. The outer end portions
15 of the upper arm may be flexed outwardly into a cocked
16 position, whereby the catch member rests on a pressure
17 release member and is held there by engagement of the
18 release member with the catch member. By applying downward
19 pressure on the lancing blade arm, the outer flexible
20 portion of the lancing blade arm is caused to flex
21 outwardly, whereby the catch member disengages from the
22 release member and the lancing blade is propelled downward
23 through the opening to lance the skin underneath. Guide
24 sidewalls on the catch member assure proper vertical
25 movement of the lancing blade. The resiliency of the
26 trigger arm immediately pulls the lancing blade back where
27 further cocking and use may be prevented by interaction of
28 the release member with the catch member.

29 Further objects and advantages of the subject
30 invention will become apparent to those skilled in the art
31 from review of the following description, reference being
32 made to the accompanying drawings in which,

33 Brief Description of the Drawings

34 FIG. 1 is a perspective view of an embodiment of
35 the subject invention showing the lancing blade and lancing
36 opening.

1 FIG. 2 is a top view of the embodiment of FIG. 1.
2 FIG. 3 is a side view of the embodiment of
3 FIG. 1.

4 FIG. 4 is a front view of the embodiment of
5 FIG. 1, showing the positioning of the catch arm and
6 cocking arm.

7 FIG. 5 is a side view of FIG. 4.

8 FIG. 6 is a side view showing the capture of the
9 catch arm by the cocking arm after use.

10 FIG. 7 is a side view in partial cross section of
11 the embodiment of FIG. 1 in use.

12 Detailed Description of the Invention

13 Referring now to FIGS. 1 and 3, the lancing
14 device 10 of the subject invention has a pair of arms 11
15 and 12 which are generally in a V-shaped relation with one
16 another. Lower arm 12 comprises a straight base having a
17 lancing aperture 13 at one end and a cocking arm or member
18 14 as will be described later in more detail. At the
19 opposite end, base portion 12 is integrally connected to
20 upper lancet arm 11 in a V-shaped connection. Upper lancet
21 arm 11 extends outwardly from base portion 12 preferably at
22 an angle 15 of from 5° - 7°, and preferably 6°. At its
23 outer end of upper lancet arm is a resilient arcuate
24 portion 16. While shown as an arcuate or arm portion,
25 resilient arm portion 16 may take any other shape which
26 would provide increased resiliency at its outer end.
27 Preferably arcuate portion 16 has an arc length of a half
28 circle, which is disposed at an angle 17 of from about
29 25° - 35°, preferably 30°, to the upper lancet arm 11.
30 Arcuate portion is preferably a rod in cross-section with
31 a diameter of approximately 1/8".

32 Secured to the extreme outermost tip of arm
33 portion 16 is lancet blade 28 within lancet holder arm 18.
34 Arm 18 is secured to resilient arm portion 16 in its
35 midsection. Lancet blade 28 is preferably surgical steel
36 or the like, and is carried by arm 18 for travel through

1 opening 13. The entire assembly is a one-piece insert
2 injection-molded plastic piece, made as well known in the
3 art. The lancing device may be molded of a suitable
4 thermoplastic such as nylon, polyvinylchloride,
5 polyethylene, or polypropylene, preferably of
6 polycarbonate.

7 Lancing blade 28 has a sharp end which is
8 initially covered with a plastic sheath 19 which is scored
9 at its connection 24 with the lower end of the resilient
10 arm portion 16. The sheath 19 is preferably oriented so
11 that it extends radially away from the lancing blade 28 and
12 might be easily grasped and twisted off prior to use to
13 expose the sharp end thereof. Extension of sheath 19
14 radially from the plane of the lancet blade 28 permits easy
15 rotation of the sheath to break the score line and remove
16 the sheath.

17 At the lower end of arm 18 is catch arm member 30
18 which interacts with cocking arm member 31 as will be
19 described. Catch member 30 and cocking arm member 31 each
20 have mating parallel 45° generally sloped surfaces 21 and
21 22, respectively, which are in contact with one another.
22 More specifically, the upper catch arm surface 21 is
23 generally flat and at a 45° angle to the horizontal, while
24 lower cocking arm surface 22 is radiused, preferably with
25 a 14" radius. Upper catch arm surface 21 may be rounded on
26 an upper extremity. In this manner, sufficient friction is
27 exhibited between the two surfaces 21 and 22 to maintain
28 the respective arms in a cocked and ready position, yet
29 great force is not required to overcome it which actuating
30 the lancing procedure, as might be experienced with two
31 flat opposing surfaces. Guide ears 23 are positioned on
32 either side of the upper surface of catch member 20.

33 In the cocked position, the upper catch member 30
34 has a sloped contact surface 21 resting on mating sloped
35 surface 22 of the lower cocking member 14. Ears 23
36 restrict lateral movement of the catch member 20.

37 In the use and operation of the subject

1 invention, the lancet blade is exposed by twisting off
2 sheath 19. During the twisting movement of the sheath to
3 break the score line 24, lateral movement of the lancet
4 blade is restricted, as stated, so that the mating surfaces
5 do not lose contact with one another and attain a position
6 inconsistent with a proper stabbing orientation and thrust.

7 Upper arm 11 has a finger or thumb pad 25 in its
8 mid-section which permits the application of pressure in a
9 downward direction. After exposing the lancet blade by
10 removal of the sheath 19, and application of pressure on
11 the thumb pad 25, flexible member 16 flexes until
12 sufficient pressure is applied between mating surface
13 portions 21 and 22, whereupon the catch member 20 slides
14 off cocking arm surface 21 and the lancing blade snaps
15 forcefully downward and towards and through aperture 13.
16 When the lancing device 10 is placed on a finger, centering
17 the aperture 13 on the portion of the finger to be lanced,
18 as in FIG. 7, and this procedure carried out, the action of
19 the lancing blade traveling forcefully through the aperture
20 13 causes the finger to be lanced. The resilient spring
21 action of the upper arm 11 in conjunction with the
22 resilient portion 16 causes the blade to snap back, out of
23 the finger. Further movement of the lancing blade upward
24 is restricted through contact of the upper surface 26 of
25 the catch member with the lower surface 27 of the cocking
26 arm. A second use of the lancing blade is made difficult
27 by the ears which restrict lateral movement of the lancing
28 blade so that it becomes very difficult to reposition the
29 lancing blade in the cocked position. Therefore, the user
30 is encouraged to disgrace of the device after one use.

31 While the invention has been described with
32 reference to a preferred embodiment, it will be understood
33 by those skilled in the art that various changes may be
34 made and equivalents may be substituted for elements
35 thereof without departing from the scope of the invention.
36 In addition, many modifications may be made to adapt a

1 particular situation or material to the teachings of the
2 invention without departing from the essential scope
3 thereof. Therefore, it is intended that the invention not
4 be limited to the particular embodiment disclosed as the
5 best mode contemplated for carrying out this invention, but
6 that the invention will include all embodiments and
7 equivalents falling within the scope of the appended
8 claims.

9 Various features of the invention are set forth
10 in the following claims.

WHAT IS CLAIMED:

- 1 1. A disposable, single-use lancing device,
2 comprising:
3 a pair of arms integrally connected to one
4 another at an acute angle, each arm having a free end
5 portion;
6 one of said arms being a base arm and having an
7 aperture at said free end portion;
8 the other said arm being a spring arm and having
9 a resilient portion at an outer end thereof;
10 a lancing blade located on the free end portion
11 of said spring arm for reciprocal travel through said
12 aperture;
13 a catch member on said free end portion of said
14 base arm, and a stop means on said catch member extending
15 toward said spring arm;
16 a cocking member on said free end portion of said
17 spring arm;
18 said catch member engaging said cocking member to
19 restrict vertical and lateral movement of said spring arm;
20 said resilient portion allowing sufficient
21 movement of said cocking member in an outward direction
22 when sufficient downward movement is applied to said spring
23 arm so that said catch member and said cocking member
24 disengage and said lancing blade moves downward through
25 said aperture for lancing a finger.
2. The lancing device of Claim 1 wherein said
stop means has a radiused surface.
3. The lancing device of Claim 2 wherein said
cocking member has a generally flat surface opposite said
radiused stop mean.
4. The lancing device of Claim 1 wherein said
resilient portion is circular in shape with an arc length
of a half-circle.
5. The lancing device of Claim 1 wherein said
resilient portion is a rod in cross-section.

6. The lancing device of Claim 1 further including a sheath about said lancing blade, said sheath extending radially from said blade.

7. The lancing device of Claim 1 wherein said device is formed by insert-injection molding.

1 8. A lancing device, comprising:
2 a base arm having inner and outer end portions;
3 a spring arm having an inner end integrally
4 connected to said base arm inner portion at an angle of
5 about 5°-7° and having an outer spring arm portion
6 comprising a half-circle connected to an inner spring arm
7 at an angle of about 25° to about 35°;
8 an aperture on said outer end portion of said
9 base arm;
10 a lancing blade carried on said outer spring arm
11 portion for movement into and out of said aperture;
12 mating first and second stop means on said base
13 arm and said spring arm respectively, for restricting
14 movement of said spring arm relative to said base arm;
15 whereby upon application of downward force to
16 said spring arm, said first and second stop members to
17 disengage and cause said lancing blade to travel through
18 said aperture to a lancing position, and thereafter retract
19 to a nonlancing position.

9. The lancing device of Claim 8 wherein said first and second stop members have opposing angled surfaces.

10. The lancing device of Claim 9 wherein said second stop member has a pair of ears on an outer portion thereof for restricting lateral movement of said lancing blade.

11. The lancing device of Claim 8 wherein said outer spring arm is a rod in cross-section.

12. The lancing device of Claim 8 further including a removable sheath about said lancing blade.

13. The lancing device of Claim 8 wherein said device is formed by insert-injection molding.

14. The lancing device of Claim 8 wherein said device is formed of polycarbonate.

15. The lancing device of Claim 8 wherein said outer spring arm comprises a 1/8" rod.

16. The lancing device of Claim 8 wherein said inner spring arm tapers in width, the end adjacent to said outer spring arm portion being wider than the opposing end.

1 17. A lancing device, comprising:
2 a base arm having inner and outer end portions;
3 a spring arm having an inner end integrally
4 connected to said base arm inner portion and having an
5 outer spring arm portion comprising a semi-circle connected
6 to an inner spring arm;
7 a pair of ears on said outer spring arm;
8 an aperture on said outer end portion of said
9 base arm;
10 a lancing blade carried on said outer spring arm
11 portion for vertical movement into and out of said
12 aperture, said ears restricting lateral movement of said
13 blade while permitting said vertical movement;
14 mating first and second stop means on said base
15 arm and said spring arm respectively, for restricting said
16 vertical movement of said spring arm relative to said base
17 arm;
18 whereby upon application of downward force to
19 said spring arm, said first and second stop members to
20 disengage and cause said lancing blade to travel through
21 said aperture to a lancing position, and thereafter retract
22 to a nonlancing position.

18. The lancing device of Claim 17 wherein said first and second stop members have opposing angled surfaces, one of which is radiused and the other of which is flat.

FIG. 1

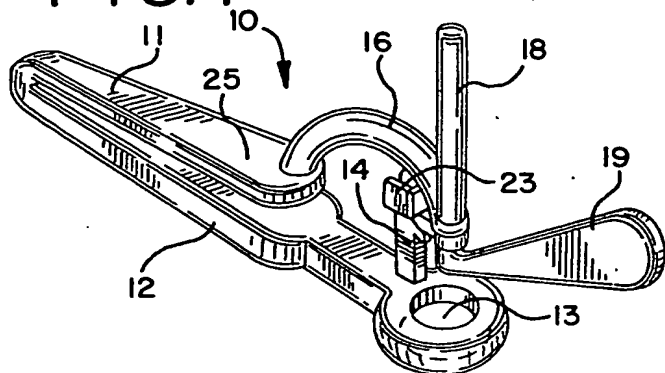


FIG. 2

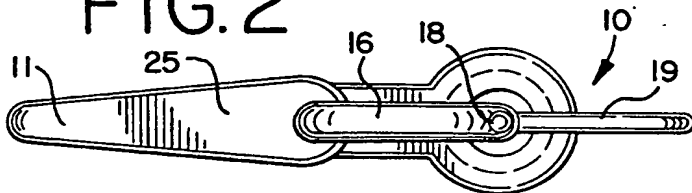


FIG. 3

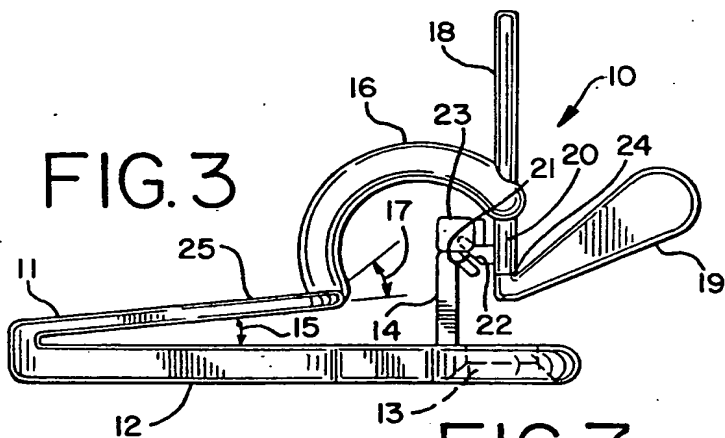


FIG. 7

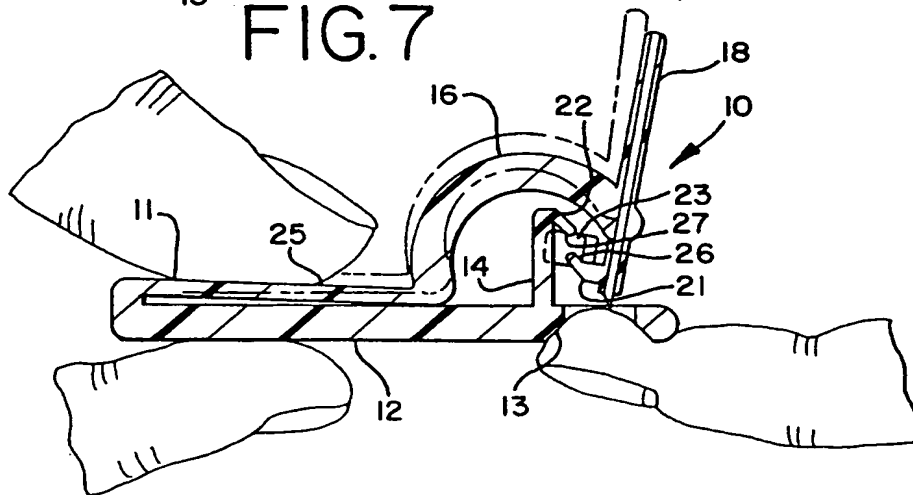


FIG. 4

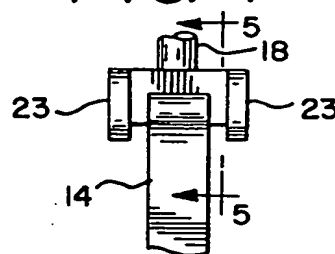


FIG. 5

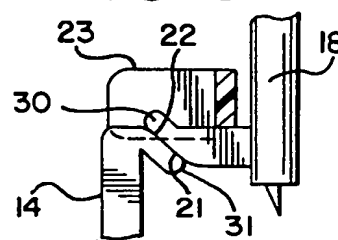
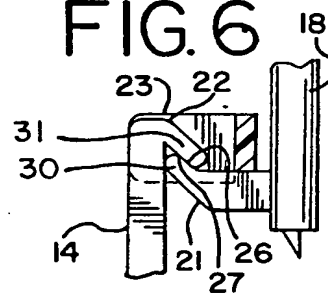


FIG. 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/12098

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/32

US CL :606/167, 181, 182, 185

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/770; 604/115, 117, 158, 162, 171; 606/167, 172, 181-185, 188

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
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NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,983,178, (SCHNELL), 08 January 1991. See entire document.	1-3, 5 ----- 4, 6, 7, 17, 18
Y	US, A, 4,191,190 (HASTINGS), 04 March 1980. See column 2, lines 17-19.	4, 17, 18
Y	US, A, 4,452,243, (LEOPOLDI ET AL.), 05 June 1984. See column 5, lines 23-27.	6
Y	US, A, 4,980,109, (YAMAMOTO ET AL.), 25 December 1990. See entire document.	7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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